

### REMARKS

The claims have been amended in order to more completely describe and distinctly claim the invention and to overcome the various grounds of rejection set forth in the Official Letter. Thus, the claims have been amended to indicate that the antioxidant is an extract of a member of the family Labiatae or an active antioxidant ingredient thereof. Support for the amendatory subject matter concerning the natural antioxidant may be found in the paragraph bridging pages 4 and 5 and in previous claims 2, 7, 12 and 18. Support for the amendatory subject matter concerning the definitions of the flavor and fragrance compounds may be found at page 2, second paragraph. Inasmuch as no new matter is embodied by the proposed amendments, entry thereof is respectfully requested.

The rejection of the claims under 35 USC 112, first paragraph, on the ground that the specification does not enable the claims is believed to be obviated by the above amendment, whereby the claims have been amended to indicate that the natural antioxidant is an extract of a member of the family Labiatae or an active antioxidant ingredient thereof. The Examiner's attention is directed to the statement in paragraph 1 of the Official Letter to the effect that the specification is enabling for such a definition of the antioxidant. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of claims 1-4 under 35 USC 102 over Chang et al as being completely anticipated is respectfully traversed insofar as this ground of rejection is directed to the claims as presently amended). The Examiner states (paragraph 2) that Chang et al"

*"---teaches natural antioxidant stabilizing flavor composition and preventing deterioration of oils and fats in food products---*"

It is respectfully submitted that the claims, as presently amended, are not anticipated by Chang et al. Thus, the reference to Chang does not mention color-stabilization and is limited to the treatment of oils and fats wherein color-stabilization is usually not a factor. The

present claims are drawn to the stabilization of fragrance and/or flavor compounds having at least one color component sensitive to electromagnetic radiation against color degradation. Thus, as noted by the Examiner, the claims specify “an amount (of stabilizer) sufficient to substantially stabilize said fragrance or flavor composition against color degradation”. Since Chang does not disclose the stabilization of anything against color degradation and, further, since the only materials disclosed by Chang are fats and oils that do not contain color components sensitive to electromagnetic radiation, the reference cannot be said to anticipate the claimed invention.

The limitation in the claims, “in an amount sufficient to substantially stabilize said fragrance or flavor composition against color degradation” cannot be ignored in evaluating the claims in light of the disclosure of Chang et al. Should the Examiner be of the opinion that the claims are met by Chang on the ground that both are directed to compositions containing similar ingredients and that the only difference between the two is the intended use recited in the claims, it is respectfully submitted that another difference exists between the two. Thus, whereas Chang describes compositions comprising similar compositions, the present claims are drawn to compositions stabilized against color degradation, a utility not disclosed by Chang.

More importantly, Chang does not disclose an “an amount sufficient to substantially stabilize (anything) against color degradation”. Inasmuch as the latter is an essential element of the invention and is a positive limitation recited in the claim, it is not seen how the claim can be rejected over prior art that does not disclose or remotely suggest the same.

Any attempt by the Examiner to simply state that an “intended use” limitation is not a positive limitation for purposes of distinguishing a claim over a reference, however, overlooks the recitation in the claims of an amount of the stabilizer effective to render the composition stable against color degradation. Since Chang does not specify the amount of the

stabilizer necessary to guard against color degradation, it cannot be said to disclose or suggest the claimed composition.

Thus, the body of each of the claims defines an “an amount” of the stabilizer sufficient to impart color stability. This is a limitation of the claims which cannot be ignored. The Examiner will not be able to demonstrate that Chang is even aware that the stabilizers disclosed therein possess this utility much less teach an amount required to produce the desired effect.

Attention is also directed to the decision in *Ex parte Skuballa*, 12 USPQ2d 1570 (PTOBPAI, 1989) which acknowledges that the phrase “effective amount” is a critical limitation in a claim having a definite meaning which cannot simply be ignored. Chang does not recognize the color stabilization effect stated in the claims and does not disclose the effective amounts for producing this result. Therefore the intended use language of the claims and the effective amounts recited in the claim are material to the structural difference between the claimed invention and the prior art necessary to patentably distinguish the claimed invention from the prior art.

It is, of course, also well settled in the law that a reference must enable the practice of a claimed invention before it can be said to disclose or suggest the invention. *In re Legrice*, 133 USPQ 365; *Phillips v. Ladd*, 138 USPQ 421; *Dupont v. Ladd*, 140 USPQ 297; *In re Brown*, 141 USPQ 245; *In re Foster*, 145 USPQ 166; *In re Dow*, 5 USPQ2d 1529. Since the present claims specify amounts of the compounds effective for color stabilization, for example, and the reference relied upon sets forth no such amounts it cannot be said to anticipate the invention. It is also well settled that “a prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation” (*Minnesota Mining and Manufacturing Co. v. Chemique, Inc.* 303 F3d 1294, 64 USPQ2d 1270 (Fed. Cir. 2002)).

In *In re Wands*, 858 F.2d 721, 8 USPQ2d 1400 (Fed. Cir. 1998), it is stated that the factual premises of enablement in a prior art reference may include the following:

- (1.) the quality of experimentation necessary;
- (2.) the amount of direction and guidance given;
- (3.) the nature of the invention;
- (4.) the state of the prior art;
- (5.) the relative skill of those in the art;
- (6.) the predictability or unpredictability of the art; and
- (7.) the breadth of the claims.

It is readily apparent that Chang fails on all seven counts to qualify as an enabling disclosure of the claimed invention since the specified amounts of the stabilizer are not set forth. See also *In re Grose*, 201 USPQ 57, and *In re Wiggins*, 179 USPQ 421.

Attention is also directed to the decision in *Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research*, 68 USPQ2d 1373 (CAFC, Nov., 2003) wherein the CAFC held that the disclosure of an assertedly anticipating prior art reference must be adequate to enable possession of desired subject matter, and a reference that merely names or describes the desired subject matter thus does not anticipate it if the subject matter cannot be produced without undue experimentation, stating:

*“---To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. ‘A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled.’ [Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). See Bristol-Myers Squibb v. Ben Venue Laboratories, Inc., 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) (‘To anticipate the reference must also enable one of skill in the art to make and use the claimed invention.’); PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) (‘To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.’) ---Enablement requires that ‘the prior art reference must teach one of ordinary skill in the art to*

*make or carry out the claimed invention without undue experimentation.* ' [Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1369, 52 USPQ2d 1129, 1134 (Fed. Cir. 1999) ('Whether undue experimentation would have been required to make and use an invention, and thus whether a disclosure is enabling under 35 U.S.C. § 112, 11, is a question of law that we review de novo, based on underlying factual inquiries that we review for clear error.')] (See also) *In re Goodman*, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993). --- *The principles underlying application of the criteria of enablement to the content of the prior art were discussed in In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985): 'It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling. It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.' Id. at 533, 226 USPQ at 621. See also *In re Borst*, 345 F.2d 851, 855, 145 USPQ 554, 557 (CCPA 1962) ('the disclosure must be such as will give possession of the invention to the person of ordinary skill. Even the act of publication or the fiction of constructive reduction to practice will not suffice if the disclosure does not meet this standard.'). --- *The determination of what level of experimentation is "undue," so as to render a disclosure non-enabling, is made from the viewpoint of persons experienced in the field of the invention. See Enzo Biochem, supra*: 'The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art.' *In re Wands*, 8 USPQ2d 14001 (Fed. Cir. 1988). *In Wands the court observed that* '[t]he test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed' quoting *In re Jackson*, 217 USPQ 804, 817---

Clearly, the weight of authority supports the proposition that a reference that does not enable one skilled in the art to possess what is allegedly disclosed does not disclose it within the meaning of the patent laws. Since Chang does not enable a composition containing the critical amounts of stabilizer, the reference cannot be said to anticipate, either expressly or inherently, the claimed invention. Stated differently, a nonenabled disclosure cannot be said to anticipate anything.

Since, therefore, applicant has established the “effective amount” of stabilizer to enhance color stability as a critical “structural difference” between the present claims and Chang, withdrawal of this ground of rejection is respectfully requested.

The rejection of claims 1, 2, 3, 6, 7 and 8 under 35 USC 102 over Todd et al as being completely anticipated is respectfully traversed insofar as this ground of rejection is directed to the claims as presently amended for the reasons stated above in connection with the rejection based on Chang et al. In addition, Todd also requires the presence of a “non-ionic surface active agent” to achieve color stabilization. Todd et al state at column 2, lines 13-23 and lines 63-69, respectively:

“---The heart of the invention lies in the totally unexpected effect which certain, but not all, emulsifiers have upon the stability of these pigments. As described hereinafter, these emulsifiers are not antioxidants, and indeed may have a slight pro-oxidant effect when added to vegetable oils. Accordingly, the stabilizing effect must be attributed to an unknown mechanism, such as inhibition of electron transfer in the pigment when it quenches singlet oxygen, which then renders it more immune to the attack of oxygen---”;

and

“---The stability of annatto, tomato, carrot, marigold, and synthetic carotenoid pigments, when subjected to oxidative and thermal stress, is markedly increased by admixing them with certain emulsifiers, which emulsifiers are not antioxidants but rather affect the stability of the pigments in some other, unknown, manner---”.

Obviously, Todd et al teach away from the present invention which does not rely on the presence of surface active agents to achieve color stabilization. Moreover, the claims have been amended to exclude the surface active agents disclosed by Todd et al as critical the invention disclosed thereby.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of claims 1-9 under 35 USC 102 over Bank et al as being completely anticipated is respectfully traversed insofar as this ground of rejection is directed to the claims as presently amended for the reasons stated above in connection with the rejections

based on Chang et al and Todd et al. Thus, Bank does not discuss color-stabilization and does not disclose the amounts of stabilizer to achieve such an effect. Accordingly, for the reasons discussed above, withdrawal of this ground of rejection is respectfully requested.

The rejection of the claims over 35 USC 103 as obviously unpatentable over Chang et al, Todd et al and Bank et al is respectfully traversed insofar as this ground of rejection is directed to the claims as presently amended. The above-discussed fatal deficiencies of the individual references are not cured by combining the disparate teachings thereof to arrive at the claimed invention. The Examiner must, in order to piece together the individual teachings of the reference to come up with the claimed invention, ignore limitations disclosed by the references as otherwise critical to the success of the inventions disclosed therein.

It is well settled that the prior art must suggest the desirability of combining references to reject claims. See *Ex parte Walker*, 135 USPQ 195 and *Ex parte Fleischmann*, 157 USPQ 155. In order to justify a combination of references, it is necessary not only that it be physically possible to combine them, but also that the art should contain something to suggest the desirability of doing so. The prior art cannot be combined as if appellant's invention was included therein as a part of the knowledge possessed by one of ordinary skill in the art. In combining references, the prior art references themselves must suggest their being combined so as to render the claimed invention obvious to one skilled in the art; and resort must not be had to applicant's own disclosure and the utilization of hindsight for the guiding hand that dictates the combination of references.

In determining the propriety of a rejection under 35 U.S.C. § 103, it is well settled that the obviousness of an invention cannot be established by combining the teachings of the prior art absent some teaching, suggestion or incentive supporting the combination. See *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir.

1985); ACS Hospital Systems. Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). The law is that “a case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.” In re Rinehart, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976). See also In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984) (“In determining whether a case of *prima facie* obviousness exists, it is necessary to ascertain whether the prior art teachings would appear to be sufficient to one of ordinary skill in the art to suggest making the claimed substitution or other modification.”).

It is only by using applicants’ own teachings and relying upon impermissible hindsight that one versed in the art would have been led to even contemplate combining the teachings of Chang, Todd and Banks. In this regard, the authorities are unanimous in holding that it is impermissible to use the claimed invention as an instruction manual or “template” to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious. A rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Since there is no factual basis in the prior art relied on which supports the proposed combination thereof, and it is apparent that the examiner’s conclusion of obviousness is based on hindsight reconstruction of the claimed invention from isolated disparate teachings in the prior art, this ground of rejection is not sustainable.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Application Serial No. 10/062,561  
Amdt. dated August 19, 2004  
Reply to Office Action of May 19, 2004

Applicants have earnestly endeavored to place this application in condition for allowance and an early action to that end is respectfully requested.

Respectfully submitted,

Miles & Stockbridge, P.C.

A handwritten signature in black ink, appearing to read 'Dennis P. Clarke', with a stylized, flowing script.

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